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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION *This document relates to* IMOGENE ROBERTSON, ALPHONSO BRADLEY AND LEROY BRADLEY, DECEASED Plaintiffs, vs. PFIZER, INC. Defendant	MDL Docket No. 1699 CASE NO. 3:07-cv-2532-CRB **PFIZER INC.'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

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DEFENDANT PFIZER INC.'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.) ("Pfizer" or "Defendant") and files this its Original Answer to Plaintiffs Original Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Decedent was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Decedent was prescribed and used Bextra®.

II.

ORIGINAL ANSWER

1. Defendant admits that Plaintiffs brought this civil action seeking monetary damages, but denies that Plaintiffs are entitled to any relief or damages. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Decedent's date of Death and whether Decedent used Bextra® and therefore denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct and denies the remaining allegations contained in this paragraph of the Complaint.

2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' citizenship and the amount in controversy, and therefore denies the same. However, Defendant admits that Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds $75,000, exclusive of interests and costs.

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3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant is without knowledge or information sufficient to form a belief as to the judicial district in which the asserted claims allegedly arose and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States, including Texas, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies committing a tort within the State of Texas and denies the remaining allegations in this paragraph of the Complaint.

4. Defendant admits that Pfizer is a Delaware corporation with its principal place of business in New York, that it is registered to do business in Texas, and that it may be served through its registered agent. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

5. Defendant admits that it does business in the State of Texas. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States, including Texas, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

6. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' and Decedent's citizenship, and therefore denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

7. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Decedent's medical condition and whether Decedent used Bextra®, and therefore denies the same. Defendant denies that

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Bextra® caused Plaintiffs or Decedent injury or damage and denies the remaining allegations in this paragraph of the Complaint.

8. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

9. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies that Bextra® caused Plaintiffs or Decedent injury or damage and denies the remaining allegations in this paragraph of the Complaint.

10. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

11. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® (valdecoxib) is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in

accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

12. Defendant states that, as stated in the FDA-approved labeling for Bextra®, "[t]he mechanism of action of Bextra is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Bextra does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® (valdecoxib) is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

13. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

14. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

15. Defendant denies the allegations in this paragraph of the Complaint.

16. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law.

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Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

17. Defendant states that the allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. To the extent that a response is deemed required, Defendant admits that Vioxx® was withdrawn from the United States market on September 30, 2004. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

18. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

19. Defendant states that the referenced article speaks for itself and respectfully refers the Court to the article for its actual language and full text. Any attempt to characterize the article is denied. Defendant admits that the sale of Bextra® was voluntarily suspended in the United States market as of April 7, 2005. Defendant denies the remaining allegations in this paragraph Complaint.

20. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA.

21. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

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22. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

23. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®, and denies the remaining allegations in this paragraph of the Complaint.

24. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

25. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

26. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

27. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies

any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

28. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

29. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

30. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

31. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendant admits that it has duties as are imposed by law but denies having breached such duties. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

32. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

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33. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

34. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies the allegations in this paragraph of the Complaint.

35. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

36. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

37. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

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38. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

39. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

40. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

41. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

42. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that

the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

43. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

44. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

45. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

46. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

47. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 47 of the Complaint, Defendant states that this paragraph of the Complaint contains legal contentions to which no

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response is deemed required. To the extent a response is deemed required, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra® and therefore denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

48. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 48 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

III.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products.

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Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiffs' action is barred by the statute of respose.

Seventh Defense

7. Plaintiffs' claims against Defendant are barred to the extent Plaintiffs and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

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Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendant affirmatively denies that they violated any duty owed to Plaintiffs or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Decedent's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

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Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Ninetieth Defense

19. Plaintiffs and Decedent knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

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Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

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Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Texas, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Texas law.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

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Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Texas. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate

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advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs and Decedent have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not

having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs and Decedent, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedent did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

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Forty-eighth Defense

48. The claims must be dismissed because Decedent would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedent.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the

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Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiffs' claims.

Fifty-sixth Defense

56. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code § 82.007.

Fifty-seventh Defense

57. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code § 82.003.

Fifty-eighth Defense

58. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code § 16.012.

Fifty-ninth Defense

59. This action is subject to the proportionate responsibility provisions of Chapter 33 of the Texas Civil Practice and Remedies Code, including (without limitation) the requirement of § 33.003 thereof that the trier of fact determine the relative responsibility of each claimant, defendant, and responsible third-party that may be joined in the suit.

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Sixtieth Defense

60. If Plaintiffs settle with any other person or entity, then Defendant reserves the right to make a written election of credit for settlements under § 33.014 of the Texas Civil Practice and Remedies Code.

Sixty-first Defense

61. Plaintiffs' recovery, if any, from Defendant should be reduced by the comparative negligence, fault, responsibility, or causation attributable to other defendants.

Sixty-second Defense

62. Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

Sixty-third Defense

63. Plaintiffs' claims are barred in whole or in part because any alleged defect was not known or not reasonably scientifically knowable at the time the product was distributed.

Sixty-fourth Defense

64. Plaintiffs' claims are barred by their failure to comply with conditions precedent to the right to recover.

Sixty-fifth Defense

65. Plaintiffs' claims are barred in whole or in part by the doctrine of informed consent. Decedent was informed of the risks associated with treatment and willingly consented to treatment despite those risks. Specifically, Decedent gave informed consent to the prescribing physicians before taking Bextra®, alone or in combination with any other drug(s).

Sixty-sixth Defense

66. The duty to obtain Decedent's informed consent prior to prescribing Bextra® alone or in combination with any other drug(s) rested solely with the prescribing physicians.

Sixty-seventh Defense

67. Plaintiffs may not assert a claim against Defendant for negligent misrepresentation as Plaintiffs and Decedent did not suffer a pecuniary loss as a result of any alleged misrepresentation by Defendant.

Sixty-eighth Defense

68. Plaintiffs' claims of negligent misrepresentation are barred by the failure to justifiably rely on any alleged misrepresentation of Defendant.

Sixty-ninth Defense

69. Plaintiffs' claims of misrepresentation are barred because any alleged misrepresentation on which Plaintiffs and Decedent relied did not constitute a misrepresentation of material facts.

Seventieth Defense

70. Plaintiffs and Decedent did not rely on any alleged express or implied warranty.

Seventy-first Defense

71. Plaintiffs and Decedent failed to notify Defendant of any alleged breach of warranty within a reasonable time after they discovered or should have discovered any such alleged breach and are, therefore, barred from any recovery for such claims.

Seventy-second Defense

72. Defendant specifically denies that it received any notice of any alleged breach of warranty from Plaintiffs or Decedent within a reasonable time after Plaintiffs and Decedent discovered or should have discovered any such alleged breach and Plaintiffs and Decedent are, therefore, barred from any recovery for such claims.

Seventy-third Defense

73. Plaintiffs' claims for breach of warranty are barred in whole or in part by the Defendant's disclaimers.

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Seventy-fourth Defense

74. Plaintiffs' claims for breach of warranty are barred in whole or in part because they are not in privity with Defendant.

Seventy-fifth Defense

75. Defendant asserts the defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proved.

Seventy-sixth Defense

76. Plaintiffs' claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance and/or usage of trade.

Seventy-seventh Defense

77. Defendant expressly denies that any third party engaging in the acts alleged by Plaintiffs were acting as defendant's agent or servant, at the instruction of defendant, or within the defendant's control. Therefore, Plaintiffs' claims, to the extent they seek recovery for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

Seventy-eighth Defense

78. Plaintiffs' claims are barred in whole or in part by the doctrine of federal preemption. The manufacture, marketing, and labeling of Bextra® was and is controlled by federal law, and Defendant was at all times in compliance and obedience with applicable federal law. If Plaintiffs' causes of action against Defendant are permitted and allowed, they would impede, impair, interfere with, frustrate and/or burden the effectiveness of federal law regulating the field of prescription drugs and would constitute an invalid burden on interstate commerce, violating the supremacy and commerce clauses of the United States Constitution, Article VI, Section 2 and Article I, Section 8, respectively, as set forth in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Plaintiffs' claims, in whole or in part, are preempted, or barred by applicable federal law, including any claim based in whole or in part on:

(a) any allegation of negligence *per se* or that Defendant violated federal regulations, including any regulations promulgated or enforced by the Food and Drug Administration;

(b) any allegation that Defendant committed "fraud" on, or otherwise misled, made misrepresentations to, concealed material information from, or violated reporting requirements imposed by any agency of the federal government, including the Food and Drug Administration;

(c) any allegation that Bextra® was not "safe and effective" or that the risks of the drug outweighed its benefits;

(d) any allegation that Defendant failed to give Decedent's healthcare providers adequate warnings concerning the risks associated with Bextra®; and/or

(e) any allegation that, if accepted, would impose standards of care in addition to, or different from, those imposed by federal law, including federal regulations promulgated by the Food and Drug Administration.

Seventy-ninth Defense

79. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Eightieth Defense

80. Plaintiffs' claims are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

Eighty-first Defense

81. Plaintiffs have failed to allege conduct warranting imposition of punitive damages under Texas law.

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Eighty-second Defense

82. The standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do not include amounts intended as exemplary damages, which are impermissible in a compensatory damages award.

Eighty-third Defense

83. Plaintiffs' claims for non-pecuniary damages are unconstitutionally vague and/or overbroad, and are in contravention of Defendant's rights under each of the following constitutional provisions:

(a) the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;

(b) the Takings Clause of the Fifth Amendment of the United States Constitution;

(c) the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;

(d) the Equal Protection Clause of the Fourteenth Amendment; as well as the various provisions of the Texas Constitution, including but not limited to art. I §§ 3, 13, 14, 16 and 19.

Eighty-fourth Defense

84. As set forth in *BMW of North America v. Gore*, 116 S. Ct. 1489 (1996) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003), the Due Process Clause of the United States Constitution protects Defendant from any award of damages that:

(a) is based, in whole or in part, on conduct which did not harm Plaintiffs and Decedent;

(b) is based, in whole or in part, on conduct and/or harm that occurred wholly outside Texas;

(c) is based, in whole or in part, on conduct that is the exclusive province of federal law;

(d) is based, in whole or in part, on comparisons of the relative wealth of Defendant and Plaintiffs and Decedent; or

(e) is grossly disproportionate to the harm suffered by Plaintiffs and Decedent.

Because the standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, they are inadequate to ensure that such awards are not based on impermissible considerations. Any award of non-pecuniary damages in this case would therefore be in contravention of the Due Process standards set forth in *BMW of North America v. Gore*, 116 S. Ct. 1489 (1996) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003).

Eighty-fifth Defense

85. Plaintiffs' claims for punitive or exemplary damages are subject to the limitations and requirements of Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008(b).

Eighty-sixth Defense

86. Plaintiffs' claims for punitive damages are in contravention of Defendant's rights under each of the following constitutional provisions:

(a) the Commerce Clause of Article I, Section 8 of the United States Constitution;

(b) the Contracts Clause of Article I, Section 10 of the United States Constitution;

(c) the prohibition against *ex post facto* laws embodied in Article I, Section 10 of the United States Constitution;

(d) the Supremacy Clause of Article VI of the United States Constitution;

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(e) the Free Speech Clause of the First Amendment of the United States Constitution;

(f) the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;

(g) the Takings Clause of the Fifth Amendment of the United States Constitution;

(h) the Right to Counsel of the Sixth Amendment of the United States Constitution;

(i) the Excessive Fines Clause of Eighth Amendment of the United States Constitution;

(j) the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;

(k) the Equal Protection Clause of the Fourteenth Amendment;

(l) as well as the various provisions of the Texas Constitution, including but not limited to Art. I. §§ 3, 13, 14, 16, and 19.

Eighty-seventh Defense

87. Because of the lack of clear standards, the imposition of punitive damages against Defendant is unconstitutionally vague and/or overbroad.

Eighty-eighth Defense

88. No act or omission of Defendant was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

Eighty-ninth Defense

89. To the extent Plaintiffs' claim for punitive damages is premised on alleged violations of FDA regulations, such claim is preempted by federal law and by the authority set out in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

Ninetieth Defense

90. With respect to Plaintiffs' demand for punitive damages, Defendant specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of *BMW of North America v. Gore*, 517 U.S. 559 (1996) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

V.

PRAYER

WHEREFORE, Defendant prays that Plaintiffs take nothing by their suit; that Defendant be discharged with its costs expended in this matter, and for such other and further relief to which it may be justly entitled.

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July 6, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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